Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

PRD2009-11

Proposed Registration Decision

Bifenazate

(publié aussi en français)

10 September 2009

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

HC Pub: 8346

ISBN: 978-1-100-13219-8(978-1-100-13220-4)
Catalogue number: H113-9/2009-11E (H113-9/2009-11E-PDF)

Table of Contents

Overview

Proposed Registration Decision for Bifenazate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Bifenazate Technical (Registration Number 27923), Acramite 50 WS (Registration Number 27925) and Floramite SC (Registration Number 27924). Acramite 50 WS , containing the technical grade active ingredient bifenazate, is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Bifenazate Technical, Acramite 50 WS and Floramite SC are conditionally registered in Canada. The detailed review of these products can be found in Regulatory Note REG2006-01, *Bifenazate*. The current applications were submitted to convert Bifenazate Technical, Acramite 50 WS and Floramite SC from conditional registration to full registration.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the review of the data submitted in support of the applications to convert Bifenazate Technical, Acramite 50 WS and Floramite SC from conditional to full registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "The product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment, particularly those most sensitive to environmental contaminants. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of the Health Canada website at healthcanada.gc.ca/pmra.

Before making a final registration decision on bifenazate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Registration Decision on bifenazate, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Bifenazate?

Bifenazate is the active ingredient in the end-use products Acramite 50 WS and Floramite SC. Acramite 50 WS is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

Health Considerations

Can Approved Uses of Bifenazate Affect Human Health?

Bifenazate is unlikely to affect your health when used according to label directions.

Potential exposure to bifenazate may occur through the diet (food and water) or when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive subpopulations in humans, such as children and nursing mothers.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose at which no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when bifenazate products are used according to label directions.

The technical grade active ingredient bifenazate caused allergic skin reactions in animals. Consequently, the statement "Potential Dermal Sensitizer" is required on the label for the technical grade active ingredient.

Bifenazate did not cause cancer in animals and was not genotoxic. There was also no indication that bifenazate caused damage to the nervous system and there were no effects on reproduction. When bifenazate was given to pregnant animals, no effects on the developing fetus were observed at doses that were toxic to the mother, indicating that the fetus was not more sensitive to bifenazate than the adult animal. The primary health effects in animals given daily doses of bifenazate over longer periods of time were effects on blood cell formation and development. Additional effects included effects on the liver, kidney, adrenals and mammary gland. The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation that would ingest the most bifenazate relative to body weight, are expected to be exposed to less than 26% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from bifenazate is not of concern for all population sub-groups. Bifenazate is not carcinogenic; therefore, a chronic cancer dietary risk assessment is not required.

Animal studies revealed no acute health effects. Consequently, a single dose of bifenazate is not likely to cause acute health effects in the general population, including infants and children.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout Canada and the United States using bifenazate on apples, grapes, greenhouse cucumbers, greenhouse pepper, greenhouse tomatoes, and strawberries were acceptable. The MRLs for this active ingredient can be found in the Science Evaluation of this consultation document.

Occupational Risks From Handling Acramite 50 WS and Floramite SC

Occupational risks are not of concern when Acramite 50 WS and Floramite SC are used according to label directions, which include protective measures.

Direct skin contact can occur when workers mix, load or apply either Acramite 50 WS or Floramite SC and when workers re-enter freshly treated fields, greenhouses, shadehouses and interiorscapes. Therefore, during mixing/loading or applying Acramite 50 WS or Floramite SC, and during clean-up and repair activities, workers must wear chemical resistant gloves, a long sleeved shirt, long pants, socks and shoes.

As a result of the evaluation of new data, risk to workers who re-enter treated fields was reassessed for all uses currently on the labels of Acramite 50 WS and Floramite SC. The personal protective measures on the labels were updated accordingly. Taking the updated label requirements into consideration, risk to workers handling product or exposed to areas freshly treated with Acramite 50 WS or Floramite SC is not of concern.

For bystanders, exposure is expected to be much less than for field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Bifenazate Is Introduced Into the Environment?

Bifenazate and its transformation products are rapidly transformed in the environment and are non-persistent. They have a low potential for residue carryover. They also have a low potential to leach and contaminate groundwater. Bifenazate is moderately toxic to bees and the use of Acramite 50 WS will pose a risk to predatory and parasitic arthropods, and mammals on a dietary and reproductive basis. Bifenazate is highly toxic to freshwater and marine invertebrates and fish and the use of Acramite 50 WS may pose a risk to these organisms. Floramite SC will pose a risk to aquatic organisms if the greenhouse effluents are discharged into the aquatic systems. These risks have been mitigated by the addition of environmental hazard label statements.

Value Considerations

What Is the Value of Bifenazate?

Acramite 50 WS is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Acramite 50 WS and Floramite SC to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health
During mixing/loading or applying Acramite 50 WS or Floramite SC, and during clean-up and repair activities, workers must wear chemical resistant gloves, a long-sleeved shirt, long pants, shoes and socks.

After application of Acramite 50 WS, workers must not enter treated fields:

- For 5 days after application if cane turning and girdling grapes;
- For 1 day after application if hand harvesting, tying, pruning, training, leaf pulling, and hand thinning grapes; and
- For 12 hours after application if conducting other activities.

Workers must not enter treated fields for 12 hours after the application of Floramite SC.

Environment
The following label statements are required to minimize the potential risk to terrestrial and aquatic organisms with the use of Floramite SC and Acramite 50 WS :

***Floramite* SC**
- A statement is required to mitigate risk to aquatic organisms through discharge.

Acramite 50 WS
- Precautionary statements are required to mitigate risks to beneficial or parasitic arthropods and aquatic organisms.
- Buffer zones of two or three metres are required, depending on the application method and use site.

Next Steps

Before making a final registration decision on bifenazate, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications. The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on bifenazate (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Bifenazate

1.0 The Active Ingredient, Its Properties and Uses

Refer to Regulatory Note REG2006-01, *Bifenazate* for a detailed assessment of the chemical properties of bifenazate and the end-use products Acramite 50 WS and Floramite SC.

2.0 Methods of Analysis

Refer to REG2006-01 for a detailed assessment of the methods of analysis of bifenazate and the end-use products Acramite 50 WS and Floramite SC.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

Refer to REG2006-01 for a detailed toxicological assessment of Bifenazate Technical, Acramite 50 WS and Floramite SC.

3.2 Determination of Acute Reference Dose

Refer to REG2006-01 for the determination of acute reference dose of Bifenazate Technical, Acramite 50 WS and Floramite SC.

3.3 Determination of Acceptable Daily Intake

Refer to REG2006-01 for the determination of acceptable daily intake of Bifenazate Technical, Acramite 50 WS and Floramite SC.

3.4 Occupational and Residential Risk Assessment

3.4.1 Toxicological Endpoints

Refer to REG2006-01for the toxicological endpoints for bifenazate.

3.4.1.1 Dermal Absorption

A dermal absorption value was determined and described in REG2006-01.

3.4.2 Occupational Exposure and Risk

Dermal and inhalation exposure to bifenazate is possible for chemical handlers mixing/loading and applying Acramite 50 WS or Floramite SC. Workers re-entering treated areas are potentially exposed mainly via the dermal route. All expected exposure scenarios are considered short- to intermediate-term in duration.

3.4.2.1 Mixer/Loader/Applicator Exposure and Risk Assessment

Risk to workers from dermal and inhalation exposure during mixing/loading and applying Acramite 50 WS or Floramite SC was assessed in REG2006-01, and was not found to be of concern if workers follow label directions.

3.4.2.2 Postapplication Exposure and Risk

Bifenazate has a very low vapour pressure ($<1.33 \times 10^{-7}$ kPa) and is, therefore, considered non-volatile in both indoor and outdoor settings. Due to bifenazate's low vapour pressure, postapplication inhalation exposure is expected to be insignificant relative to dermal exposure. Therefore, only postapplication dermal exposure was quantified.

New data were submitted to estimate postapplication exposure and risk. As such, new postapplication risk assessments have been conducted for Acramite 50 WS and Floramite SC.

Acramite 50 WS
Acramite 50 WS will be applied once per season using airblast application equipment. The product will be applied at a maximum rate of 3 pouches/0.8 ha (0.421 kg a.i./ha).

For grapes, a range of re-entry activities take place at different stages of cultivation. Cane turning, girdling, hand harvesting, tying, pruning, training, leaf pulling and hand thinning are generally identified as frequent activities involving high levels of foliar contact. In Canada, however, cane turning and girdling are not frequent activities. Cane turning, which is conducted only on red table grapes, is the cutting of the green canes hanging down by the grape bunches. Cane turning is not considered a major re-entry activity for grape production in Canada, as table grapes form a very small portion of Canada's grape industry. Girdling is the removal of a ring of bark from the trunk, arm or cane below the fruit that it is intended to affect. Girdling occurs once a year during a two-week period. Re-entry workers are assumed to work an eight-hour day, with exposures expected to be short- to intermediate-term in duration on a daily basis.

For apples, a range of re-entry activities take place at difference stages of cultivation. Hand thinning, pruning and harvesting are identified as frequent activities involving high levels of foliar contact. Other re-entry activities such as scouting, weeding and irrigation occur less frequently and involve lower levels of foliar contact. Re-entry workers are assumed to work an eight-hour day, with exposures expected to be short- to intermediate-term in duration on a daily basis.

To estimate exposure to bifenazate residues during postapplication activities, dislodgeable foliar residue (DFR) data were used. The postapplication exposure from grape re-entry activities was estimated using the grape DFR study described in REG2006-01. To estimate the postapplication exposure from apple re-entry activities, data from a new DFR study conducted on apples were used.

A DFR study was submitted to estimate dislodgeable foliar residues and their dissipation on foliage of apple trees after the application of Acramite 50 WS at two test sites in New York and Washington State. One application at 560 g bifenazate/ha was made to trees (5.6 $\mu g/cm^2$; the Canadian rate is 4.26 $\mu g/cm^2$). Dislodgeable residues were monitored prior to application, right after application (three to nine hours postapplication), and at 1, 2, 4, 7, 10, 21, 28 and 35 days postapplication. Out of the two trials, the highest peak mean residue value was 1.4 $\mu g/cm^2$ (25% of the application rate), which was observed right after application at the New York test site. Dissipation rates were modelled using first-order kinetics, resulting in poor R^2 values (0.59 and 0.56 for the New York and Washington sites, respectively).

The application method, frequency, monitoring times and use pattern of the study were relevant to the Canadian registered use pattern. The application rate in the study was higher than the Canadian registered rate, which results in a conservative estimate of expected DFR values. This study was considered relevant to Canadian growing regions since climate analysis and regulatory guidance show that the regions within eastern and western United States, in which the DFR trials were conducted, are within or beside corresponding regions in Canada. Thus, the trials should be considered a reasonable representation of the most important apple-growing regions in Canada as well as the United States.

The study had major limitations which rendered some data unusable. The lab and field recoveries and storage stability were poor. In addition, rainfall occurred at both sites one day after application. Due to the study limitations, the dissipation data were not used for the risk assessment. Instead, the default value of 10% dissipation per day was used. However, the data of this study, despite its limitations, suggested a peak DFR higher than the default value of 20% of the application rate. Therefore, the peak DFR found in the study (25% of the application rate) was considered appropriate to use.

To estimate the potential exposure of re-entry workers, the DFR was coupled with activity-specific transfer coefficients. The exposure estimates were compared to the no observed adverse effect level (NOAEL) of 80 mg/kg bw/day from the 21-day dermal toxicity study in rats to calculate the margins of exposure (MOE) for each re-entry activity. The target MOE for short-

term and intermediate-term exposures is 100. Inadequate MOEs were obtained for performing certain activities immediately after application. The MOEs for current uses on the label for Acramite 50 WS are considered acceptable with changes in the restricted-entry intervals (REIs). Daily exposure and MOEs of re-entry workers to bifenazate residues from Acramite 50 WS are summarized in Appendix I. Table 3.4.2.2.1 displays the new REIs for Acramite 50 WS.

Table 3.4.2.2.1 Restricted-Entry Intervals for Acramite 50 WS

Crop	Re-entry Activity	Restricted-Entry Interval (REI)
Grapes	Cane turning, girdling	5 days
	Hand harvesting, tying, pruning, training, leaf pulling, hand thinning	1 day
	Other activities	12 hours
Apples	All activities	12 hours

Floramite SC

Floramite SC will be applied once per crop cycle to all types of indoor ornamental plants in greenhouses, shadehouses and interiorscapes. Floramite SC will be diluted at a rate of 133 mL/400 L water and applied as a foliar spray at up to 2000 L/ha. Cultivation of ornamentals in general, and cut flowers in particular, involves a number of re-entry activities with high postapplication exposure potential. These tasks include pruning, pinching, thinning and hand harvesting. Cultivation of cut flowers also involves bunching and bundling. It is assumed that workers conduct re-entry activities for 8 hours/day for 6 to 7 days per week; the range of re-entry activities and the types of plants handled vary throughout the day and from day to day, and re-entry activities are highly dependent on crop stage. Duration of exposures ranges from intermediate- to long-term (for example, 5 to 12 months per year). Exposures would be intermittent to continuous (every day) and are predominantly dermal.

To estimate exposure to bifenazate residues during postapplication activities involving indoor ornamentals, data from a submitted DFR study conducted on peace lilies were used to estimate DFRs and their dissipation. Two test plots, one treated and one untreated, were established in separate greenhouses. The treated test plot was treated three times at 28-day intervals at a rate of 305 g bifenazate/ha. DFR levels were monitored before and 12 hours after after each application on the application day and on days 1, 3, 7, 14, and 21. Days 28 and 35 after the third application were also monitored. The highest mean residue was 0.144 $\mu g/cm^2$ (4.7% of the application rate), which was observed one day after the first application.

The product tested in the DFR study (a wettable powder) was different from Floramite SC; however, the application method, application rates, and monitoring times were the same or higher than proposed. The highest mean DFR (0.144 $\mu g/cm^2$) was considered to be an acceptable estimate of dislodgeable residues resulting from the proposed use of bifenazate on ornamental plants in Canadian greenhouses.

To estimate the potential exposure of greenhouse re-entry workers, the actual DFR value from the study was coupled with transfer coefficients for ornamentals and cut flowers. The risk estimates were calculated using the NOAEL of 80 mg/kg bw/day from the 21-day dermal toxicity study in rats to calculate the MOEs for each re-entry activity. Because exposures are expected to be intermediate to long-term in duration, the target MOE is 300. Daily exposure and MOEs of greenhouse re-entry workers to bifenazate residues from Floramite SC are summarized in Appendix I.

The MOEs for greenhouse workers conducting re-entry activities on greenhouse ornamentals are acceptable.

Risk to workers conducting re-entry activities on plant interiorscapes was not quantified. However, as re-entry activities with plant interiorscapes are expected to involve less foliar contact for less than 8 hours/day, the daily exposure to workers handling treated interiorscapes is expected to be less than exposures in a greenhouse setting. An REI of 12 hours is considered adequate for all re-entry activities involving ornamentals in greenhouses, shadehouses and interiorscapes.

3.5 Food Residues Exposure Assessment

Refer to REG2006-01 for a detailed food residue exposure assessment of Bifenazate Technical, Acramite 50 WS and Floramite SC.

4.0 Impact on the Environment

Refer to REG2006-01 for a detailed environmental assessment of bifenazate and the end-use products Acramite 50 WS and Floramite SC.

5.0 Value

Refer to REG2006-01 for a detailed assessment of the value and efficacy of bifenazate.

Acramite 50 WS is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

6.0 Pest Control Product Policy Considerations

Refer to REG2006-01 for detailed information regarding the Pest Control Product Policy Considerations of Bifenazate Technical, Acramite 50 WS and Floramite SC.

7.0 Summary

7.1 Human Health and Safety

The nature of the residues in plants and animals is adequately understood. The residue definition in plant matrices is bifenazate and the metabolite D3598. The residue definition in animal matrices is bifenazate and the metabolites D3598, A1530 and A1530-sulfate. The proposed uses of bifenazate and the associated Floramite SC and Acramite 50 WS end-use products do not constitute an unacceptable chronic dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed, and no new MRLs are needed.

Direct skin contact can occur when workers mix, load or apply either Acramite 50 WS or Floramite SC and when workers re-enter freshly treated fields, greenhouses, shadehouses and interiorscapes. Therefore, during mixing/loading or applying Acramite 50 WS or Floramite SC, and during clean-up and repair activities, workers must wear chemical resistant gloves, a long-sleeved shirt, long pants, shoes and socks.

As a result of the evaluation of new data, risk to workers who re-enter treated fields was reassessed for all uses currently on the labels of Acramite 50 WS and Floramite SC. The personal protective measures on the labels were updated accordingly. Taking the updated label requirements into consideration, risk to workers handling product or exposed to areas freshly treated with Acramite 50 WS or Floramite SC is not of concern.

For bystanders, exposure is expected to be much less than that of field workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

7.2 Environmental Risk

For a summary of the environmental risk assessment, please refer to REG2006-01.

7.3 Value

Bifenazate is the active ingredient of two end-use products, Acramite 50 WS and Floramite SC. Acramite 50 WS can be used to control selected mites on apples and grapes, while Floramite SC can control selected mites on greenhouse ornamentals, including shadehouses and interiorscapes.

8.0 Proposed Regulatory Decision

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Bifenazate Technical (Registration Number 27923) and Acramite 50 WS (Registration Number 27925) and Floramite SC (Registration Number 27924). Acramite 50 WS , containing the technical grade active ingredient bifenazate, is used to control European red mite, two-spotted spider mite and McDaniel mite (apples only) on apples and grapes, while Floramite SC is used to control two-spotted spider mite and Lewis mite on greenhouse ornamentals, including shadehouses and interiorscapes.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

µg	microgram(s)
a.i.	active ingredient
ARTF	Agricultural Re-entry Task Force
bw	body weight
cm	centimetres
DEEM	dietary exposure evaluation model
DFR	dislodgeable foliar residue
g	gram(s)
ha	hectare(s)
hr	hour(s)
kg	kilogram(s)
kPa	kilopascal(s)
L	litre(s)
mg	milligram(s)
mL	millilitre(s)
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
PMRA	Pest Management Regulatory Agency
REI	restricted-entry interval

Appendix I Tables and Figures

Table 1 Exposure and Margins of Exposure for Workers Conducting Re-entry Activities on Grapes and Apples After Application of Acramite 50 WS

Re-entry Activity	TC (cm^2/hr)[a]	DFR ($\mu g/cm^2$)[b]	Days Postapplication	Exposure (mg/kg bw/day)[c]	MOE[d,e]
Grapes (juice, wine, table)					
Cane turning and girdling	19 300*	0.894	0	1.972	41
		0.762	1	1.681	48
		0.698	2	1.540	52
		0.479	3	1.057	76
		0.284	5	0.627	128
Hand harvesting, tying, pruning, training, leaf pulling, hand thinning	8500*	0.894	0	0.868	92
		0.762	1	0.740	108
Hand line irrigation	1100	0.894	0	0.112	712
Scouting and hand weeding	700	0.894	0	0.072	1119
Apples					
Hand thinning	3000	1.065	0	0.365	219
Hand harvesting	1500	1.065	0	0.183	438
Hand line irrigation	1100	1.065	0	0.134	598
Hand pruning, scouting, pinching, tying, training	500	1.065	0	0.061	1315
Hand weeding, propping, animal control	100	1.065	0	0.012	6573

[a] Transfer coefficients, based on Agricultural Re-entry Task Force (ARTF) data. The applicant, Chemtura Canada Co., is a member of ARTF. Note: some of the grape TCs (with asterisks *) have changed since the original risk assessment in REG2006-01

[b] Dislodgeable foliar residue. **Grapes:** DFR values were directly from the grape DFR study. DFR values were not adjusted for application rate. **Apples:** Based on the apple DFR study, a DFR value of 25% of the application rate was used; however, since the study dissipation data was deemed unusable, the default DFR dissipation value of 10% per day was used.

[c] Exposure estimates were calculated using the following formula:

$$\frac{\text{DFR Value } (\mu g/cm^2) \times \text{Transfer Coefficient } (cm^2/hr) \times \text{Hours Worked (hr/day)} \times \text{Conversion Factor (1 mg/1000 } \mu g)}{\text{Body weight (kg)}}$$

Calculations were based on an 8-hour work day and 70 kg body weight. The dermal absorption value of 35% was determined for bifenazate; however, no adjustment of exposure data for dermal absorption is required since the NOAEL is based on a dermal toxicity study.

[d] The MOE is based on a NOAEL of 80 mg/kg bw/day from the 21-day dermal toxicity study in rats.

[e] The target MOEs for short-term and intermediate-term exposures is 100.

Table 2 Exposure and Margins of Exposure for Workers Conducting Re-entry Activities on Ornamentals in Greenhouses, Shadehouses and Interiorscapes After Application of Floramite SC

Re-entry Activity	Transfer Coefficient (cm^2/hr)[a]	Daily Dose[b,c] (mg/kg bw/day)	MOE[d]
Cut flowers- all activities	4000*	0.0658	1220
Potted plants- all activities	400*	0.00658	12 200

[a] Transfer Coefficients, based on Agricultural Re-entry Task Force (ARTF) data. The applicant, Chemtura Canada Co., is a member of ARTF. Ornamental TCs have changed since the original risk assessment in REG2006-01

[b] Dislodgeable foliar residue (DFR) was based on the highest mean DFR value from the greenhouse DFR study (0.144 $\mu g/cm^2$)

[c] Exposure estimates were calculated using the following formula:

$$\frac{\text{DFR Value } (\mu g/cm^2) \times \text{Transfer Coefficient } (cm^2/hr) \times \text{Hours Worked (hr/day)} \times \text{Conversion Factor (1 mg/1000 } \mu g)}{\text{Body weight (kg)}}$$

Calculations were based on an 8-hour work day and 70 kg body weight. The dermal absorption value of 35% was determined for bifenazate; however, no adjustment of exposure data for dermal absorption is required since the NOAEL is based on a dermal toxicity study.

[d] MOE is based on a NOAEL of 80 mg/kg bw/day from the 21-day dermal toxicity study in rats; the target MOE for long-term exposures is 300.

References

A. List of Studies/Information Submitted by Registrant

1.0 Human and Animal Health

PMRA Document Number: 1117381
Reference: 2005, Acramite (UCC-D2341) 50WS on Apples: Dislodgeable Foliar Residue Study, RGC-99-R03; DNJ-99-110, DACO: 5.9

PMRA Document Number:1117382
Reference: 1999, Floramite 50WP on Staphiphyllum: Dislodgeable Foliar Residue Study, 98-150, MRID: 44859701,45052329, DACO: 5.9

PMRA Document Number: 1294460
Reference: 2006, Clarifications for Dislodgeable Foliar Residue Study of Floramite 50WP on Spathiphyllum, DACO: 5.9

PMRA Document Number: 1294466
Reference: 2006, Clarification for Dislodgeable Foliar Residue Study of Acramite 50WS on Apples, DACO: 5.9